

The Role of Institutionalized Validation in Integrating Emerging Science into Regulatory Decision-Making

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Alternative testing strategies to whole animal test methods provide a promising means to predict possible hazards from emerging technologies, such as nanomaterials, and from conventional chemicals. The Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) is an interagency coordinating committee tasked with reviewing/evaluating alternative test methods for regulatory uses. As our analysis will show, there are no requirements that a test method be recommended by ICCVAM before being used by the EPA or another agency. Nor does a recommendation by ICCVAM guarantee that a test method will be accepted and then actually used by an agency. Some have argued that the creation of ICCVAM and other validation authorities has become a barrier to test method adoption and acceptance by agencies. Test methods may not be submitted for fear of rejection. Once submitted, it may take years before a test method is recommended to agencies. The perception of ICCVAM and validation as being a barrier to alternative testing methods will be explored to examine whether endorsement (or lack of endorsement) of new testing methods impacts the achievement of the goals put forth in the National Research Council Report entitled *Toxicity Testing in the 21st Century: A Vision and a Strategy*.